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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,447	11/30/2001	Nathan Andrew Shapira	UF-260XC1	3440
23557	7590	02/18/2004		
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION 2421 N.W. 41ST STREET SUITE A-1 GAINESVILLE, FL 326066669			EXAMINER SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 02/18/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/997,447

Applicant(s)

SHAPIRA ET AL.

Examiner

Phyllis G. Spivack

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 11 December 2003 and 05 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-10 and 33-45 is/are pending in the application.
- 4a) Of the above claim(s) 33-39 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-10 and 40-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 and 2/504.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Applicants' Amendment filed December 11, 2003 under 37 CFR 1.111 is acknowledged. New claims 30-32 were presented. Further, a Supplemental Amendment filed February 5, 2004 under 37 CFR 1.111, wherein new claims 33-45 were presented and claims 19-32 were canceled, is acknowledged. Accordingly, Claims 6-10 and 33-45 are now present in the case.

Newly submitted claims 33-39 and 45 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Methods of treating dermatological injury or tissue damage comprising administering a composition comprising an agent of Formula I require further consideration and search.

Since Applicants have received an Action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-39 and 45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, claims 6-10 and 40-44 are presently under consideration wherein topiramate is the anticonvulsant agent administered in a method for promoting wound healing.

The references for the Information Disclosure Statement previously designated as Paper No. 5 have been reviewed. An additional Information Disclosure Statement filed February 5, 2004 has been considered. Because previous initialed Form PTO-1449 sheets are no longer available to the Examiner, Applicants are urged to check at this time for completeness of all Information Disclosure Statement information of record.

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In the last Office Action claims 6-10 were rejected under judicially created doctrine as being drawn to an improper Markush group. It was asserted a common nucleus is absent among the various compounds encompassed in instant Formula I when  $X_1$  is  $CH_2$  or oxygen in a ring to which methylenedioxy groups may optionally be fused.

Applicants consider the issue resolved following an amendment.

Applicants' amendment has not resolved the issue of a lack of a common nucleus among the claimed compounds. The rejection of record is maintained for the reasons of record and presently extended to include new claims 40-43.

Claims 6-10 were rejected in the last Office Action under 35 U.S.C. 103 as being unpatentable over Blake et al., WO 00/10610. It was asserted Blake teaches the topical administration of topiramate as an anti-convulsant therapeutic agent linked to a non-cytotoxic bio-reductive moiety for promoting wound healing.

Applicants argue Blake teaches topiramate for use in the treatment of epilepsy, not for the healing of wounds through a topical administration. Further Applicants urge there is no motivation to use topiramate in wound healing because such pharmacological activity does not appear to have been recognized.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record under 35 U.S.C. 103 is repeated for the reasons of record and is presently extended to include new claims 40-44.

Independent claim 1 is not limited to topical administration. Motivation to administer topiramate to promote wound healing flows from both the discussion on

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pages 4-14 of Blake's teaching clearly directed to wound healing and also the inclusion of the known anti-epileptic agent topiramate.

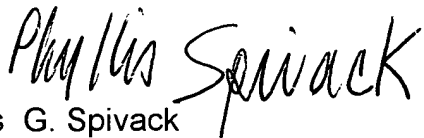
No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Phyllis G.

Spivack at telephone number 703-308-4703.

  
Phyllis G. Spivack  
Primary Examiner  
Art Unit 1614

February 13, 2004

**PHYLLIS SPIVACK**  
**PRIMARY EXAMINER**